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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,389	10/29/2003	Lawrence T. Boni	TRANS-008	6398

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,389	BONI ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9-26-05, 6-23-07.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims included in the prosecution are 1-25.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between treatment and ameliorating in the independent claims and some dependent claims is unclear. Since the dictionary meaning of the term, 'ameliorating' is 'improving', which is the same as treating, the term is redundant.

It is unclear whether the terms in parenthesis are indeed the limitations as recited in claim 14. 'e.g.' renders claim 14 indefinite since it is not a positive recitation.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lagace (5,662,929).

Lagace teaches that chronic lung infection due to P. aeruginosa is a major cause of morbidity and mortality in patients with cystic fibrosis. According to Lagace P aeruginosa colonizes more than 90 % cystic fibrosis adolescents. Lagace teaches the encapsulation of amino glycosides in liposomes for the treatment of P. aeruginosa infections. One of the modes of administration taught by Lagace is aerosol (abstract, col. 3, line 7 through col. 6, line 16; col. 7, line 40 through col. 8, line 15; Examples). According to instant claims, the 'dosing is once a day or two days or **less'**. The term, 'less' includes even one dose. Therefore, the reference meets the requirements of instant claims.

5. Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Gonda et al (US 2005/0019926).

Gonda et al while disclosing liposomal formulations containing amino glycosides. According to Gonda et al, such formulations can be used for treatment of bacterial diseases in cystic fibrosis patients. The amino glycosides include tobramycin and amikacin. The composition is administered by pulmonary route (0011, 0027, 0060-0066, 0070 and 0089). As pointed out above, according to instant claims, the 'dosing is once a day or two days or **less'**. The term, 'less' includes even one dose. Therefore, the reference meets the requirements of instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonda et al (US 2005/0019926).

Gonda et al while disclosing liposomal formulations containing amino glycosides. According to Gonda et al, such formulations can be used for treatment of bacterial diseases in cystic fibrosis patients. The amino glycosides include tobramycin and amikacin. The composition is administered by pulmonary route (0011, 0027, 0060-0066, 0070 and 0089). What is lacking in Gonda et al is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

8. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beaulac et al (Journal of Drug targeting, 1999 of record by itself or in combination with Gonda et al cited above.

Beaulac et al disclose a method of treating chronic pulmonary infection caused by Pseudomonas aeruginosa by the administration of liposomal tobramycin (abstract, Experimental Design and Results). What is lacking in Beaulac et al is the claimed

protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results. Beaulac et al do not teach that the host infected with this organism has also cystic fibrosis. However, since the composition of Beaulac et al is effective against this organism, it would have been obvious to one of ordinary skill in the art that the composition would be effective against this organism irrespective of whether the patient is suffering from other conditions. One of ordinary skill in the art would be motivated to use the compositions of Beaulac et al to treat the infection caused by this organism in cystic fibrosis patients with a reasonable expectation of success since the reference of Gonda et al the liposomal administration of amino glycoside to cystic fibrosis patients.

9. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lagace (5,662,929).

Lagace teaches that chronic lung infection due to P. aeruginosa is a major cause of morbidity and mortality in patients with cystic fibrosis. According to Lagace P aeruginosa colonizes more than 90 % cystic fibrosis adolescents. Lagace teaches the encapsulation of amino glycosides in liposomes for the treatment of P. aeruginosa infections. One of the modes of administration taught by Lagace is aerosol (abstract, col. 3, line 7 through col. 6, line 16; col. 7, line 40 through col. 8, line 15; Examples). What is lacking in Lagace is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day

and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

10. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen (US 2003/0118636) in view of Lagace (5,662,929).

Friesen teaches lipid vesicles for the delivery of drugs. According to Friesen, in the lungs the pH of the airway surface liquid is reduced in subjects with inherited and acquired diseases such as cystic fibrosis and asthma as a result of lung obstruction, infection and inflammation and since not all lobes of the lung are affected at the same time, the use of lipid vesicles including pH-sensitive drug release channels may improve the therapeutic index of a drug administered by inhalation (0025). What is lacking in Friesen is the teaching of instant amino glycosides. Inclusion of amino glycosides in the liposomes of Friesen for the treatment of pulmonary infections in cystic fibrosis patients would have been obvious to one of ordinary skill in the art since the reference of Lagace shows that these antibiotics are effective against several pulmonary organisms causing the infection. What is also lacking in Friesen is the claimed protocol of administration as claimed in instant claims. However, whether the composition has to be administered daily or once a day and the dosage depend upon the severity of the condition, the age of the patient and other parameters, they are deemed to be obvious parameters manipulated by an artisan to obtain the best possible results.

Double Patenting

11. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 74-76, 78-84, 86-87, 94-95, 98-102 and 105-108 of copending Application No. 10/383,173 by itself or in combination with Lagace cited above. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in both are drawn to a method of treatment of diseases caused by the same organisms using the same liposomal compositions containing the same active agents. Instant claims recite the limitation that the patients having these organisms in addition suffer from cystic fibrosis. Since the active agents used are for the treatment of the infective disease itself and not the additional disease conditions the patient is suffering from, it would have been obvious to one of ordinary skill in the art to use the compositions irrespective of other disease conditions the patient is suffering from. One of ordinary skill in the art would be motivated to treat the same infective disease in cystic fibrosis patients since the reference of Lagace teaches that 90 % of cystic fibrosis patients are infected with P aeruginosa and that liposomal compositions containing the antibiotics could be used for the treatment.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The reference of Dale (6,211,162) is cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK